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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,598	11/12/2005	Moti Harel	026086.095-35US	6923

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,598	HAREL ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-64* is/are pending in the application.

4a) Of the above claim(s) *35-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed December 16, 2008 has been received, entered and carefully considered. The response affects the instant application accordingly:

a. Claim 60 has been amended.

2. Claims 34-64 are pending in the case.

3. Claims 60-64 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

Information Disclosure Statement

5. The information disclosure statement filed February 17, 2006 and August 7, 2006 continued to not be considered as there is no translation present for the non-patent literature by Cannizares-Villanueava et al. and the EP 0410236.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 60-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to “an algal derived DHA-rich phospholipid”. The term is unclear because it can be interpreted where the phospholipids are completely from the algae or

a mix with a DHA extract from algae and a phospholipid source. The specification addresses an algal phospholipid but the LC-PUFA phospholipid or the phospholipid is either a non-algal source mixed with the marine biomass oil or the non-algal source (please see paragraph 72 and 76). It is confusing as the specification does not support a phospholipid purely from algae without the use of a separate phospholipid in its production. The art also addresses the inclusion of phospholipids into the plankton biomass prior to processing to yield phospholipids from algae. If the phrase is viewed as phospholipids purely from the biomass without the use of phospholipids of any sort in any form of processing, it would be viewed as new matter. The phrase is unclear if it is a mix or pure form of algae without other phospholipids. The term of DHA-rich is also relative as what degree is viewed as DHA-rich which is unclear.

It does not allow one of skill of the art to ascertain the metes and bounds of the invention. For the purposes of prosecution, any form of a phospholipid with any aspect of algae/biomass oil in any form applies.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 60-61, 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto (JP 06-070698) in view of Borror et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585).

A human translation is provided; all references are to the translation.

Sugimoto teaches a method of making a feed additive for fish for improving meat quality and color. Sugimoto teaches formulating the feed additive by blending 100g of phospholipid with 0.1-10g of carotenoid. The additive is then added to the feed where the composition comprises at least 2g phospholipid (at least 2% of the feed) and at least 3mg carotenoid (at least .03% of carotenoid) per 100g of feed. The addition is 0.1g/100g feed to 10g/100g feed and the preferred range of phospholipid is 2g to 10g phospholipid/100g feed. The claimed range for the carotenoid in the feed is at least 3mg carotenoid in 100g of feed (see full translation, specifically Abstract, Claim 4, Paragraph 5-6,10-12).

The carotenoids taught for use are astaxanthin, canthaxanthin, zeaxanthin, and beta-carotene, among others. Sugimoto also teaches a carotenoid complex (which would include more than one carotenoid) can be used. The phospholipid predominately used is lecithin and preferably in oil form. If a powder form was used, oil such as vegetable, soybean, corn, olive, and others would be used to dilute the powder to form an oil to be added in the feed.

The carotenoid and phospholipid are mixed, then a binder and vegetable feed are added, and the feed in fabricated into pellet form to be used as feed. Sugimoto states that the amounts can change with concentration and fish stocks.

Sugimoto does not expressly teach the lowest limitation of a carotenoid to be at least 1%, the phospholipid at least 5%, the inclusion of a phospholipid with algae material.

Borror et al. (U.S. Pat. 6036992) teaches that phospholipids can be derived from analogous sources including egg yolk, soy bean, and microbial single cell oils such as algal oils. Borror teaches that the microbial single cell oils may be used, particularly for the AA and DHA fatty acid components of phospholipids (Col. 5 line 24-31).

Gladue et al. teaches that aquaculture feed need to be nutritionally balanced so that the fish larvae receive proper nutrition and DHA (docosahexenoic acid) significantly contribute to larval growth and survival which ultimately is acquired from algae. Gladue teaches that if sufficient DHA is provided to the larvae, the survival rate would increase, reducing the cost of farm-raised seafood (Page 1 line 27- Page 2 line 8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the amounts of the carotenoid and phospholipid, as suggested by Sugimoto, and use a phospholipid from an algae source as suggested by Borror and Gladue, and produce the instant invention.

While Sugimoto does not expressly state the range of a carotenoid to be at least 1%, it is encompassed by the range taught by Sugimoto. Sugimoto teaches that the composition comprises at least 2g phospholipid (at least 2% of the feed) and at least 3mg carotenoid (at least 0.003% of carotenoid) per 100g of feed. Sugimoto also claims the carotenoid to be at least 3 mg per 100g of feed and the phospholipid to be at least

2g per 100g of feed. It would have been obvious to one of skill in the art to adjust and optimize the amount of carotenoid dependent on the animal to be fed or the components of the feed and particularly, to increase and optimized the amount of carotenoid to improve the color in the animal meat (e.g. salmon) as it is visually more appealing to consumers. The amount of phospholipid would increases proportionally as the additive requires blending 100g of phospholipid with 0.1-10g of carotenoid.

It is also obvious to one of skill in the art to utilize other analogous phospholipid sources such as algae, as Borror teaches that phospholipids can be drawn from several analogous sources such as egg yolk, soy bean, and algal oils. Borror also teaches that microbial single cell oils such as algal would be used for the AA and DHA fatty acid components of phospholipids. It would be obvious to one of skill in the art to use algal phospholipids for the AA and DHA for the feed as Gladue et al. teaches that aquaculture feed need to be nutritionally balanced so that the fish larvae receive DHA (docosahexenoic acid) which significantly contributes to the larval growth and survival, and as the survival rates increase, it reduces the cost of farm-raised seafood.

One of skill in the art would have been motivated to do this because it is routine in the art to optimize the feed to attain the desired improved color and qualities in the fish and greater and improved color in the animal meat such as salmon is visually more appealing to consumers and would produce more sales. The improved and greater concentration of color would be easily accomplished by the increase of the carotenoids in the feed. One of skill in the art would have been motivated to also use algal oil infused phospholipids as Borror teaches them to be analogous with egg and soy

sources with the benefit of AA and DHA fatty acid components and Gladue teaches that increase DHA in the feed improves fish survival and lowers the cost of the farm-raised seafood which is desirable.

10. Claims 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto in view of Borror et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585) as applied to claims 60-61, 63-64 above, and in view of Place et al. (U.S. Pat. No. 6261590).

The teachings of Sugimoto in view of Borror et al. in view of Gladue et al. are addressed above.

Sugimoto in view of Borror in view of Gladue does not expressly teach coating the pellet with the mixture.

Place et al. teaches that drugs, vitamins, carotenoids, and/or pigments are usually added to animal feed (soap solution) before the spray drying process which would form the granules (e.g. powders, pellets, etc.). Place also teaches that the drugs, vitamins, carotenoids, and/or pigments could also be added to the feed (soap powder) after the drying step. The carotenoids and pigments included beta-carotene, cantaxanthin, astaxanthin, astaxanthin esters, zeaxanthin, among others.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to coat the pellets with the carotenoid mixture, as suggested by Place et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have several choices to modify and distribute the carotenoid/phospholipid additive depending on the degree of absorption and method of delivery used to produce the final product. If the additive is incorporated in the feed, the absorption would be delayed or time release dependent the components of the feed. If the additive was on the outer coat of the feed, then it would be immediate release in the digestive process. One would be motivated to use either method depending on the desired outcome. Additionally, many of the carotenoids taught in Place were those taught in Sugimoto showing compatibility and a reasonable expectation of success.

Response to Arguments

11. Applicant's arguments filed 12/16/2008 have been fully considered but they are not persuasive. Applicant's argument in regards to the preferred embodiment of Sugimoto is not persuasive as it does not go to the general teachings of Sugimoto including the claim range of at least 3mg carotenoid and at least 2g phospholipid in 100g of feed which encompass the instant claimed range and can be optimized from. Applicant's assertion of unexpected results is not persuasive as they are not commensurate in scope with the claims as the example addressed is using 8g of the algae phospholipid which is not represented in the claims, and the comparative is on trout while the claims encompass far broader species. As a result, the argument is not persuasive.

Conclusion

12. Claims 60-64 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612